REMARKS

Claims 1-30 are pending. Claims 1-10 were examined and rejected. Claims 11-30 were withdrawn by the Examiner.

No new matter is added.

In view of the following remarks, the Examiner is requested to allow claims 1-10.

Rejection of claims under 35 U.S.C. § 112

Claims 1-10 were rejected under 35 U.S.C § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skilled in the art that the inventors had possession of the claimed invention at the time of filing. This is a new matter rejection. The Applicants respectfully traverse this rejection.

The written description requirement of 35 U.S.C. § 112, first paragraph, involves the question of whether the subject matter of a claim conforms to the disclosure of an application as filed. According to the MPEP, an objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed?"[1] The subject matter of the claim need not be described literally (i.e. using the same terms or *in haec verba*) in order for the disclosure to satisfy the written description requirement. Likewise, MPEP states that newly added claim limitations may be supported by disclosure that is express, implicit, or inherent.[2]

Claim 1 is drawn to a method of identifying a compound capable of modulating Fcγ receptor signaling comprising: contacting a mast with IgG; crosslinking said IgG in the presence

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[1] See MPEP § 2163.02, citing *In re Gosteli* 872 F.2d 1008, 1012 (Fed. Cir. 1989).

[2] MPEP § 2163: "The written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims, which introduce elements or limitations, which are not supported by the as-filed disclosure, violate the written description requirement...While there is no *in haec verba* requirement, ***newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure***. (emphasis added)

of a candidate compound, and determining whether the candidate compound modulates the Fcγ receptor-mediated signaling.

As best understood by the Applicants, this rejection is based on the Examiner's belief that step b) of claim 1, namely: "cross-linking the IgG in the presence of a candidate compound" constitutes new matter.

In response, the Applicants submit that the cross-linking step of claim 1 is specifically supported by paragraph 99 of the specification on page 32. This paragraph describes adding a candidate compound to the wells of a 96-well plate (lines 1-2, i.e., "To duplicate 96-well U-bottom plates (Costar 3799) are added 65 ul of compound dilutions"), combining the cells with a candidate compound (lines 7-8, i.e., "To each 96-well plate is added 65 ul of cells"), and cross-linking the cells in the present of the candidate compound (lines 8-9, i.e., "After mixing four times, the cells are then…….stimulated with anti-IgE and/or IgG", where *anti*-IgE and *anti*-IgG are cross-linking agents). As such, the cross-linking step in question, i.e., "cross-linking the IgG in the presence of a candidate compound" is specifically described in paragraph 99 the instant specification.

Moreover, the specification generally describes Fcγ receptor activation (which inherently includes Fcγ receptor crosslinking) in the presence of a candidate compound at various positions, including: ¶10 on page 4 (i.e., "the treated cells are activated by stimulating Fcγ receptor signaling cascade to determine whether the candidate compound modulates….." and ¶32 on page 10 (i.e., "compounds that selectively inhibit upstream Fcγ receptor-mediated degranulation inhibit degranulation of cells….that are activated or stimulated with an IgG-specific allergen or binding agent (such as an anti-IgG antibody)". As such, in addition to being described in ¶99, step b) of claim 1, i.e., "cross-linking the IgG in the presence of a candidate compound" is described at least two other places in the instant specification.

In view of the foregoing discussion, the Applicants submit that the specification adequately describes a method that includes step b) of claim 1, i.e., "cross-linking the IgG in the presence of a candidate compound". As such, the Applicants submit that no new matter was added by the prior amendment, and this rejection should be withdrawn.

Withdrawal of this rejection is thus requested.

The Applicants respectfully requests that a timely Notice of Allowance be issued in this case.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-047.

Respectfully submitted,
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